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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,588	10/02/2003	Jingrui Wu	38-15(52578)C	7647
27161	7590	10/24/2006	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			KUMAR, VINOD	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/678,588

Applicant(s)

WU ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Petitions

1. The Office acknowledges the receipt of Applicant's petition for correction of inventorship filed April 28, 2006. Applicants urge that claims in instant application have been amended to claim subject matter that was disclosed, but not claimed, in the application originally filed, and which require correction to add inventors not named in the application (petition, 1st paragraph). However, Office denies the entry of this petition because the newly added claims 14 and 15 encompass SEQ ID NO: 2 which does not belong to elected invention and are thus withdrawn from consideration.

The Office acknowledges the receipt of Applicant's petition for amending priority filed April 28, 2006. Applicants urge that the claims have been amended to include new dependent claim directed to a plant of claim 6 comprising SEQ ID NO: 2 which was disclosed in the Application as originally filed and in US Serial No. 09/865,439 as SEQ ID NO: 119104 (petition, 2nd paragraph). However, Office denies the entry of this petition because the newly added claims 14 and 15 encompass SEQ ID NO: 2 which does not belong to elected invention and are thus withdrawn from consideration.

Election/Restriction

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previously withdrawn claims 8-13 have been rejoined in light of their amendment. Claims 1-2 and 5-13 are examined in this Office action. Applicants are advised that if any claims including all the limitations of an allowable claim examined here are presented in a continuation or divisional application, such claims may be subject to

provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The newly added claims 14 and 15 encompass SEQ ID NO: 2 which does not belong to elected invention and are thus withdrawn from consideration. This action is made **FINAL**. All previous rejections not set forth below have been withdrawn in view of amendments.

Specification

2. Specification amendment on page 9, lines 5-16 filed in the paper April 28, 2006 is objected because provisional applications become abandoned after 1 year. It is not pending. The status of provisional did not to be updated.

Claim Rejections - 35 USC § 112

3. Claims 1-2 and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

Claims 1, 5, 6 and 7 are rejected under 112, second paragraph as being indefinite in their recitation “functionally equivalent”, which is confusing since it is unclear how water-deficit tolerance produced by the expression of consensus sequence SEQ ID No: 8 is “functionally equivalent” to water-deficit tolerance produced by the expression of SEQ ID NOs: 2, 3, 6 or 7. How is the “functionally equivalent” water-deficit tolerance different from “functionally non-equivalent” water-deficit tolerance. It is unclear what is encompassed by the recitation.

4. Claims 1-2, 5-7 remain and claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, because the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record stated in Office action mailed December 29, 2005. Applicants traverse the rejection of claims 1-2 and 5-7 in the paper filed April 28, 2006.

Applicants argue that specification describes identifying and isolating DNA encoding Hap3 proteins with the consensus amino acid sequence of SEQ ID NO: 8, cloning the coding DNA into a transformation vector, transforming plant cells to produce water-deficit tolerance transgenic plants. The experimentation required is exacting but once performed is routine. The required experimentation is not so indefinite as to be undue (response, page 3, last paragraph, lines 8 through line 4 of page 4; page 4, lines 11-14).

Applicant's arguments were fully considered but were not persuasive. Hap3 protein comprising an amino acid sequence of SEQ ID NO: 8, which is a consensus of amino acid sequences of SEQ ID NOs: 2, 3, 6 and 7 encompass large number of substitutions, additions and/or deletions of more than one amino acid residues when compared to SEQ ID NOs: 2, 3, 6 or 7 individually or as a pileup. Further, SEQ ID NOs. 2, 3, 6 or 7 do not contain an amino acid sequence which has 100% sequence identity to the amino acid sequence of SEQ ID NO: 8. Neither the state of prior art nor the specification provide guidance on which region(s) of SEQ ID NOs: 2, 3, 6 or 7 are able to tolerate deletions, additions or substitutions of one or more amino acid without abrogating water-deficit tolerance activity when expressed in a transgenic plant. In this regard, Examiner maintains that teachings of Keskin et al., Thornton et al., and in

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particular Guo et al., further substantiate the significance of increased unpredictability to determine whether a protein comprising the sequence SEQ ID NO: 8 actually can produce a water-deficient tolerance phenotype when expressed in a plant. Examiner maintains that undue experimentation is required to determine whether a protein comprising a consensus sequence of SEQ ID NO: 8 is able to produce water-deficit tolerance phenotype when overexpressed in a transgenic plant. The specification does not correlate the function of conferring water deficit tolerance to the sequence set forth in SEQ ID NO: 8. The specification does not teach the importance of the sequence of SEQ ID NO: 8, to the functionality of SEQ ID NOs: 2, 3, 6 and 7. All that is indicated is that SEQ ID NO: 8 is a consensus of a portion of the sequences of SEQ ID NOs: 2, 3, 6 and 7.

Applicants argue that the plant height data on transgenic versus non-transgenic plant under water-deficit stress conditions in Table 1 is statistically significant and data in Example 2 clearly provides experimental evidence that the transgenic corn plants expressing *Hap3* (SEQ ID NO: 2) produced water-deficient tolerance phenotype (response, page 4, last paragraph through the end of line 29 of page 5).

Applicant's arguments were fully considered but were not persuasive. Examiner maintains that plant height data presented in Table 1 does not indicate that transgenic plant expressing *Hap3* protein (SEQ ID NO: 2) was significantly different than wild type plant subjected to under water-deficit stress condition. Under water deficit stress conditions, the plant height was significantly reduced to almost half both in transgenic and wild type plant. Furthermore, given that plant height ratio between a transgenic and a wild type plant remained 1.0 under stress and non-stress conditions clearly implies that said transgenic plant was not water-deficit tolerant compared to the wild type.

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Furthermore, Examiner maintains that data presented in Example 2, page 14 does not indicate that transgenic plant expressing Hap3 (SEQ ID NO: 2) exhibited water-deficit tolerance characteristics for the reasons of record stated in Office action mailed December 29, 2005. Additionally, data as disclosed in Tables 1, 2 and 3 do not describe statistical parameters such as, population size, population mean, sample size and degree of freedom which are important parameters for analyzing any data for “statistical significance”. In the absence of such guidance one skilled in the art can not conclude that a height of 20.5 cm (transgenic plant) is significantly higher than a height of 19.7 cm (wild type plant) in table 1 or a height of 33.8 cm (transgenic) is significantly higher than 32.9 cm (wild type plant) in table 2. Data presented in Tables 1, 2 and 3 implies that even SEQ ID NO: 2 does not confer water-deficit tolerance to plants. Given that data presented in tables 1, 2 and 3 do not indicate that transgenic plants expressing SEQ ID NO: 2 are water-deficit tolerant and SEQ ID NO: 2 does not comprise an amino acid sequence which is 100% identical to SEQ ID NO: 8, examiner maintains undue experimentation would have been required by a skilled artisan to determine how to use the consensus sequence of SEQ ID NO: 8 in a method of producing a water-deficit tolerant transgenic plant.

Applicants argue that Figure 1 shows that SEQ ID NOs: 2, 6 and 7 meet the requirement of being amino acid sequences comprising the consensus amino acid sequence of SEQ ID NO: 8 and provided working examples of transgenic plants and methods of making transgenic plants comprising introducing sequence comprising SEQ ID NO: 8 (response, page 6, lines 4-10).

Applicant's arguments were fully considered but were not persuasive. Examiner maintains that SEQ ID NO: 8 is not comprised within SEQ ID NOs: 2, 3, 6 or 7. SEQ ID

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NO: 8 comprises more than a single amino acid change when compared to SEQ ID NOs: 2, 3, 6 or 7. It would have been highly unpredictable that overexpression of SEQ ID NO: 8 would impart water-deficit tolerance to the transgenic plant for the reasons as discussed in Office action mailed December 29, 2005 and as discussed above.

Applicants argue that a person of ordinary skill in the art also understands that a wide range of substitutions can be made without affecting loss of phenotype. A reasonable amount of trial and error experimentation is routine in biotechnology. Reference is again made to Figure 1 which shows a number of such substitutions including insertions in the consensus amino acid sequence of SEQ ID NO: 8 (response, page 6, lines 16-22).

Applicant's arguments were fully considered but were not persuasive. Examiner disagrees with Applicants argument and maintains that specification fails to describe the regions within SEQ ID NOs: 2, 3, 6 or 7 that can tolerate mutations in one or more amino acids without abrogating water-deficit tolerance property when expressed in a transgenic plant. In the absence of guidance, examiner maintains that it is highly predictable that a non-naturally occurring protein such as the sequence SEQ ID NO: 8 would be structurally and functionally stable to produce a water-deficit tolerance phenotype when expressed in a transgenic plant. The specification does not teach the importance of SEQ ID NO: 8, or the regions of SEQ ID NOs: 2, 3, 6 and 7 to the function of Hap3 proteins. Undue experimentation would have been required by a skilled artisan to determine how SEQ ID NO: 8 can form a stable structure with water-deficit tolerance property when expressed in a cell where it is not naturally produced.

Applicants argue that the data in Tables 1-3 are part of Example 1 illustrating water-deficit tolerant corn plants while Examples 3 and 4 illustrate water-deficit tolerant

soybean plants. The Examiner's serious doubts the characteristics of the soybean plants illustrated in Examples 3 and 4 should be allayed by reading Examples 3 and 4. Statements found in Examples 3 and 4 are essentially declarations by the inventors that the soybean plants were actually water-deficit tolerant (response, pages 7-8, 2nd paragraph through the end of 2nd paragraph).

Applicant's arguments were fully considered but were not persuasive. Examiner maintains that statements made about transgenic plants with enhanced resistance to water-stress in Examples 3 and 4 are contradicted by the disclosure of data presented in Tables 1, 2 and 3 on pages 13-14 of specification. Examiner strongly maintains that the data presented in these tables gives no indication that transgenic plant are phenotypically different than non-transgenic ones when subjected to water stress. Furthermore, as discussed above, examiner maintains that data presented in Tables 1, 2 and 3 do not indicate to one skilled in the art, for example, the population size, population mean, sample size and degrees of freedom (absolutely important for any statistical analysis, emphasis added), and in the absence of such guidance one cannot conclude that a height of 20.5 cm (transgenic plant) is significantly more than a height of 19.7 cm (wild type plant) in table 1 or a height of 33.8 cm (transgenic) is significantly higher than 32.9 cm (wild type plant) in table 2. Accordingly, Examiner maintains that undue experimentation would have been required by a skilled artisan to determine how to use the consensus sequence of SEQ ID NO: 8 (derived from SEQ ID NOs: 1, 2, 3 and 7) in a method of producing a water-deficit tolerant transgenic plant. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim 12 encompasses a DNA construct which is transcribed to RNA which forms gene silencing dsRNA targeted to a crop pest. The claim encompass any and all pests. However, the specification does not teach how the dsRNA would enter the pest, and remain intact to silence the target gene. For example, the dsRNA would have to be ingested, and/or cross cell membrane barriers. Undue experimentation would have been required by a skilled artisan to determine how to design the recombinant DNA construct to transcribe dsRNA that can overcome these obstacles, for any, and all plant pests.

5. Claims 1-2 and 5-7 remain and claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention the reasons of record stated in Office action mailed December 29, 2005. Applicants traverse the rejection for claims 1-2 and 5-7 in the paper filed April 28, 2006.

In the paper filed April 28, 2006, Applicants argue that various parts of the application describe the methods and plants of the claimed subject matter by consensus amino acid sequence and water-deficit tolerance phenotype. The specification including illustrative examples clearly indicate that Applicants did, in fact have possession of the aspects of the invention (response, page 9, written description, lines 7-12). Applicants further argue that the state of art is such that a person of ordinary skill in the art understands that the full scope of genes expressing Hap3 protein comprising amino acids of the consensus SEQ ID NO: 8 covers more than four illustrative genes but extends to any gene in narrowly defined class (response, page 10, lines 11-14).

Applicant's arguments were fully considered but were not persuasive. Examiner maintains that the specification does not have adequate written description for the genus of sequences which have consensus amino acid sequence of SEQ ID NO: 8 and one skilled in the art cannot reliably predict the structures based on SEQ ID NOs: 2, 4, 6 and 7. The specification has failed to describe structures of the broadly claimed genus and correlate said structures to the function of increased water-deficit tolerance. More importantly, Applicants have failed to describe functional conserved domains shared among the undisclosed structures as encompassed by the broadly claimed genus. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. No functional significance has been correlated with SEQ ID NO: 8 by the specification.

In the paper filed April 28, 2006, Applicants quote *Capon v. Eshhar v. Dudas*, 2005 U.S. App. LEXIS 1685 to support their argument that state of art is such that a person of ordinary skill in the art understands that the full scope of genes expressing Hap3 protein comprising amino acids of the consensus SEQ ID NO: 8 covers more than four illustrative genes but extends to any gene in this narrowly defined class (page 9 last paragraph through line 13 of page 10). Applicants also cite *In Amgen Inc. v. Hoechst Marion Roussel, inc*, where court explained that the written description requirement may be satisfied "if in the knowledge of the art the disclosed function is sufficiently correlated to particular known structure" (page 10, 19-20).

Applicant's arguments were fully considered but were not persuasive. Examiner maintains that Applicants have failed to disclose the genus of sequences that comprise consensus sequence of SEQ ID NO: 8 and further failed to correlate said sequences (structures) to the function of imparting water-stress tolerance when expressed in a

plant. Structures of SEQ ID NOs: 2, 3, 6 or 7 do not comprise the consensus sequence of SEQ ID NO: 8. Furthermore, specification fails to identify functional domain(s) that are shared by these structures. Further, it is important to note that SEQ ID NO: 8 is a hypothetical sequence and encompasses large number of mutations when its sequence is compared to SEQ ID NOs: 2, 3, 6 or 7. One skilled in the art can not predictably determine the function of SEQ ID NO: 8 based on the data presented in tables 1-3 and conclusions drawn thereof in examples 3 and 4. Thus, it clearly implies that Applicants have failed to reduce their broadly claimed genus to practice. Neither the prior art nor the specification describe and correlate undisclosed Hap3 structures comprising SEQ ID NO: 8 to the function of water-deficit tolerance. Accordingly, Applicants have failed to satisfy the written description requirements cited in *Capon v. Eshhar v. Dudas*, and *In Amgen Inc. v. Hoechst Marion Roussel, inc.*

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Accordingly rejection is maintained.

Summary

6. Claims 1-2 and 5-13 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

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706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

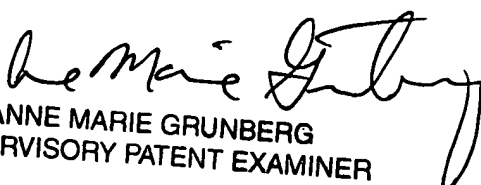
A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER

*Not Entered
V. Kumar
7/6/2006*

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APR 28 2006

In re application of: Jingrui Wu *et al.*

Art Unit: 1638

Serial No. 10/678,588

Examiner: Vinod Kumar

Filed: October 2, 2003

Docket No. 38-21(52578)C

Title: Yield-Improved Transgenic Plants

Petition to Amend Priority Under 37 C.F.R. § 1.78(a)(3)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Mail Stop Petition

Sir:

Applicants hereby petition to add priority claims in the above-captioned U.S. application under 37 C.F.R. § 1.78(a)(3).

Fee Authorization: Applicant understands 37 CFR 1.78(a)(3)(ii) to require that this petition be accompanied by surcharge set forth in § 1.17(t). The Commissioner is authorized to charge to Deposit Account No. 134125 of Monsanto Company the \$1370 fee for this petition for acceptance of an unintentionally delayed claim for priority. A duplicate copy of this Petition is enclosed.

In the amendment filed herewith (the "Amendment"), Applicants have amended the claims to include new dependent claim 14 directed a plant of claim 6 wherein said recombinant DNA comprises a promoter operably linked to native corn DNA encoding the protein with the amino acid sequence of SEQ ID NO:2 and new independent claim 15 directed to a recombinant DNA construct comprising a promoter operably linked to native corn DNA encoding the protein with the amino acid sequence of SEQ ID NO:2. Such recombinant DNA construct is disclosed in the Application as originally filed and in U.S. application Serial No. 09/865,439 where native corn DNA encoding the protein with the amino acid sequence of SEQ ID NO:2 is found in SEQ ID NO:119104. Application Serial No. 09/865,439 was copending on the October 2, 2003 filing date of this above-captioned application and later abandoned on November 18, 2003. As such, Applicants have amended

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APR 28 2006

In re application of Jingrui Wu et al.
Serial No: 10/678,588
Filed: 10/02/2003
For: Yield-Improved Transgenic Plants

Art Unit: 1638
Examiner: Vinod Kumar

Request for Correction of Inventorship under 37 C.F.R. § 1.48(c)

Commissioner for Patents

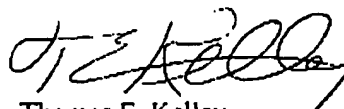
Dear Sir:

The claims in the above-referenced nonprovisional application have been amended to claim subject matter that was disclosed, but not claimed, in the application as originally filed, and which requires correction to add inventors not named in the application.

Therefore, it is hereby requested that Kristine Hardeman, Michael Edgerton and Thomas LaRosa be added as inventors for Application No. 10/678,588, by the filing of this Request which is supported by

- (1) a statement from each of the three inventors being added that their addition is necessitated by amendment of the claims and that the inventorship error occurred without deceptive intention on his or her part;
- (2) written consent of the assignee, Monsanto Technology;
- (3) a processing fee transmittal for payment of the \$130.00 processing fee specified in 37CFR 1.17(i) for correcting inventorship under §1.48; and
- (4) a declaration by the actual inventors as required by 37 C.F.R. § 1.63.

Respectfully submitted,


Thomas E. Kelley
Registration No. 29,938
Applicant's Attorney
Phone: 860-572-5274

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